

## Message Text

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43

ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 EUR-12 EA-10 NEA-09 ISO-00 OES-05

EB-07 COME-00 TRSE-00 CIAE-00 INR-07 NSAE-00 RSC-01

L-02 /076 R

66652

DRAFTED BY: DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY: OES/SCI/BMP: MBEAUBIEN

DHEW/OIH/MACODDING

ARA/NSC-IG: RJBLOOMFIELD (INFO)

EA/RA:CCHAPMAN (INFO)

EUR/NSC-IG:JROUSE (INFO)

NEA/RA:TGRANT (INFO)

EA/ROC:KWEAVER (INFO)

----- 071265

R 061447Z JAN 75

FM SECSTATE WASHDC

TO AMEMBASSY BUENOS AIRES

AMEMBASSY CANBERRA

AMEMBASSY VIENNA

AMEMBASSY BRASILIA

AMEMBASSY SANTIAGO

AMEMBASSY TAIPEI

AMEMBASSY BOGOTA

AMEMBASSY SAN JOSE

AMEMBASSY COPENHAGEN

AMEMBASSY SANTO DOMINGO

AMEMBASSY QUITO

AMEMBASSY TEGUCIGALPA

AMEMBASSY NEW DELHI

AMEMBASSY PARIS

AMEMBASSY BONN

AMEMBASSY ATHENS

AMEMBASSY GUATEMALA

AMEMBASSY SAN SALVADOR

AMEMBASSY HELSINKI

AMEMBASSY TEHRAN

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AMEMBASSY TEL AVIV

AMEMBASSY ROME  
AMEMBASSY TOKYO  
AMEMBASSY SEOUL  
AMEMBASSY BEIRUT  
AMEMBASSY KUALA LUMPUR  
AMEMBASSY MEXICO  
AMEMBASSY THE HAGUE  
AMEMBASSY WELLINGTON  
AMEMBASSY MANAGUA  
AMEMBASSY OSLO  
AMEMBASSY PANAMA  
AMEMBASSY LIMA  
AMEMBASSY MANILA  
AMEMBASSY LISBON  
AMEMBASSY PRETORIA  
AMEMBASSY MADRID  
AMEMBASSY STOCKHOLM  
AMEMBASSY BERN  
AMEMBASSY BANGKOK  
AMEMBASSY ANKARA  
AMEMBASSY LONDON  
AMEMBASSY SINGAPORE  
AMCONSUL HONG KONG  
AMCONSUL LOURENCO MARQUES

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E.O. 11652: N/A

TAGS: ETRD, TBIO, XX

SUBJ: RECALL OF MEDICAL DEVICE - BENNETT MONITORING SPIROMETER  
AND ALARM.

1. FDA ADVISES THAT THE BENNETT MONITORING SPIROMETER, CAT. NO. 2642 AND THE BENNETT SPIROMETER ALARM, CAT. NO. 5460, MANUFACTURED BY BENNETT RESPIRATION PRIDUCTS, INC., DIVISION PURITAN BENNETT CORP., OAK AT 13TH STREET, KANSAS CITY, MISSOURI 64106, HAVE MALFUNCTIONED OR FAILED IN USE AND, THEREFORE, MAY CREATE AN EMERGENCY SITUATION WHICH MAY BE LIFE-THREATENING AND COULD RESULT IN EXTREMEN NEUROLOGIC DAMAGE, CARDIAC ARREST, OR DEATH OF THE UNCLASSIFIED

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PATIENT.

2. THE BENNETT MONITORING SPIROMETER, OF WHICH AN ESTIMATED 23,400 HAVE BEEN MANUFACTURED, CONSISTS OF A CLEAR PLASTIC CYLINDER APPROXIMATELY 9" HIGH CONTAINING A GREY RUBBER COLLAPSIBLE BELLOWS AND A WHITE VALVE AND A BLACK VALVE FITTED UNDER THE BASE OF THE SPIROMETER. THE BELLOWS INSIDE THE SPIROMETER, VISUALLY SHOWS THE VOLUME OF AIR BEING DELIVERED BY AN ATTACHED VENTILATOR UNIT.

3. THE BENNETT SPIROMETER ALARM, OF WHICH APPROXIMATELY 18,000 HAVE BENN MANUFACTURED, IS USED WITH A SPIROMETER. THE ALARM IS SET AT A VOLUME SOMEWHAT LESS THAN THE OBSERVED VOLUME. IF THE BELLOWS IN THE SPIROMETER DOES NOT RISE TO THE ALARM SETTING WITHIN TWENTY SECONDS, THE ALARM SOUNDS. IF THE BELLOWS, AFTER RISING TO THE ALARM SETTING, DOES NOT EMPTY WITHIN TWENTY SECONDS, THE ALARM ALSO SOUNDS.

4. NO PHYSICAL RECALL OF THE DEVICES HAS YET OCCURRED. THE FIRM HAS SENT A LETTER TO DISTRIBUTORS REQUESTING THAT A WARNING BE ISSUED TO USERS OF THE BENNETT MONITORING SPIROMETER AND SPIROMETER ALARM THAT THEY SHOULD INSURE THE INTERGRITY OF BOTH THE EXPIRATORY DIAPHRAGM VALVE AND ITS CONNECTING TUBING WHEN CONNECTED TO ANY PRESSURE OR VOLUME VENTILATOR PRIOR TO AND DURING USE OF SUCH AN APPARATUS.

5. FOREIGN CONSIGNEES, AS FOLLOWS:

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SPITALGASSE 280 A. DIXENGOFF ST.  
VIENNA IX AUSTRIA P.O. BOX 6093  
TEL-AVIV 63117, ISRAEL

SIMONSEN & WEELS COMESA S.P.A.  
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14 ROSKILDEVEJ MILANO, ITALY  
ALBERTSLUND, DENMARK

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MEDICAL GROUP P.O. BOX 3791  
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PRIESTLY ROAD MERSTANI BUILDING  
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HAMPSHIRE, ENGLAND BEIRUT, LEBANON

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PRODUITS OCYGENES RUA NOVO DO ALMADA 61  
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75007 PARIS, FRANCE

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& BROS. CO. S-171 83 SOLNA  
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AUSTRASSE 19 SIRKECI DODUBANK  
CH-5430 WETTINGEN IS HANI N D 113  
SWITZERLAND ISTANBUL, TURKEY  
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FAR EAST:

COMMONWEALTH INDUSTR MEDICAL CENTER DRUG CORP.  
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INTERNATIONAL SDN BERHAD  
P.O. BOX 1100 P. O. BOX 639 10TH M S  
SEOUL, KOREA KLANG ROAD - SUNGEI WAY  
SELANGOR, MALAYSIA

FAR EAST OXYGEN  
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NEW ZEALAND INDUSTRIAL  
GASES LTD.  
P.O. BOX 30-337  
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PRODUCTOS FARMACEUTICOS LATIN AMER HOSP SUPPLY  
19 DE MARZO NO. 10 CORP SA - COSTADO ESTE  
SANTO DOMINGO DN PARQUE HERRERA 404  
REPUBLICA DOMINICANA TEGUCIGALPA D C  
WEST INDIES HONDURAS, C.A.

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APARTADO POSTAL 108 APARTADO 689  
SAN JOSE, COSTA RICA, C.. MANAGUA, NICARAGUA, C.A.

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CALLE 1 NO. 6 BUENOS AIRES, ARGENTINA, S.A.  
APARTADO POSTAL 1689  
PANAMA REP., DE PANAMA, C.A. SOCIEDADE COMERCIAL PRO  
MEDICO LTDA

IMDIA REA RIACHUELO 159  
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AVE 6 DE AGOSTO NO. 589 CASILLA 2158  
OF 605 SANTIAGO, CHILE, S.A  
LIMA, PERU

CASE MEDICA DOTACIONES GILCO S A  
AVE DE LAS AMERICAS APARTADO ACREO 994  
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NO. 18N-71 MEDELLIN, COLOMBIA, A.A.  
CALI, COLOMBIA, S.A.

GASES INDUSTRIALES DE OMNIA PRO MEDICO S.A.  
COLOMBIA S.A. CASILLA 575  
APARTADO AEREO 21529 QUITO, ECUADOR, S.A.  
BOGOTA, COLOMBIA, S.A.

GASES INDUSTRIALES DE VENEZUELA  
APARTADO NO. 61148  
CARACAS 106, VENEZUELA  
KISSINGER

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NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 06 JAN 1975  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1975STATE001981  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** DHEW/FDA/JRWEINROTH, M.D.  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Film Number:** D750005-0432  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1975/newtext/t19750175/aaaacodd.tel  
**Line Count:** 307  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 6  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Review Action:** RELEASED, APPROVED  
**Review Authority:** KelleyW0  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 26 FEB 2003  
**Review Event:**  
**Review Exemptions:** n/a  
**Review History:** RELEASED <26 FEB 2003 by RicharJA>; APPROVED <10 FEB 2004 by KelleyW0>  
**Review Markings:**

Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
05 JUL 2006

**Review Media Identifier:**  
**Review Referrals:** n/a  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** RECALL OF MEDICAL DEVICE - BENNETT MONITORING SPIROMETER AND ALARM.  
**TAGS:** ETRD, TBIO, XX, US, BENNETT RESPIRATION PRODUCTS INC  
**To:** BUENOS AIRES MULTIPLE  
**Type:** TE  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006